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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/177,843      | 10/22/1998  | JOHN LOIKE           | 48940-A-PCT-        | 3650             |

7590 05/02/2002  
COOPER & DUNHAM  
1185 AVENUE OF THE AMERICAS  
NEW YORK, NY 10036

EXAMINER

BANSAL, GEETHA P

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1642

DATE MAILED: 05/02/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/177843

Applicant(s)

Louke et al

Examiner

Gulther Bansa

Group Art Unit

1642

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -3- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 2/28/62
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-26, 27-39, 41; 42-54 is/are pending in the application.
- Of the above claim(s) 1-26, 42-54 is/are withdrawn from consideration.
- ☒ Claim(s) 41 (peptide of SEQ ID #2 only) is/are allowed.
- ☒ Claim(s) 27-39, is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_ ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other \_\_\_\_\_

Office Action Summary

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## **DETAILED ACTION**

### ***Continued Prosecution Application***

1. The request filed on February 28, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/177843 is acceptable and a CPA has been established. An action on the CPA follows.

Applicant's amendment filed May 3, 2001 (Paper No:13/C) is acknowledged.

Accordingly, claims 27, 39, 41 have been amended.

Claims 27-39, 41 are being examined.

### ***Response to Arguments***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Rejection of claim 27-38 under 35 U.S.C. 112, 2nd paragraph is withdrawn in view of the amendments to the claims.

### ***Claim Rejections - 35 U.S.C. § 112***

4.A. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antibody and binding fragments thereof and peptide GRGDSP, does not reasonably provide enablement for any and all agents for binding to  $\beta 1$  integrin cell surface receptor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these

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claims. The claims are drawn to a method of treating a malignant tumour by administering an agent which binds to a  $\beta 1$  integrin cell surface receptor to enhance migration of leukocytes through tenascin to reach tumour cells and kill them. The specification discloses the administration of anti- $\beta 1$  integrin antibodies or peptide GRGDSP (SEQ ID NO 2) were able to allow migration of leukocytes. The specification does not provide sufficient guidance as to other agents, peptidomimetics, peptides or how to begin to select the compounds to be tested. It appears that the claimed peptide must have the GRGDSP sequence, but the specification does not teach other peptides and how many other amino acids added to the base sequence (SEQ ID NO 2) are enabled. The peptidomimetics are a class of molecules that is understood and agreed to by Examiner as being molecules that share a conformational similarity to the selected peptides of choice. In the absence of guidance as to the making of various peptides, one of skill in the art would be forced into undue burden to determine conformational structure and then create a peptidomimetic as claimed. The conditions under which a peptidomimetic would be used in a biological system has to be compatible with the particular biological system comprising tumor cells, leukocytes or even the in vivo systems wherein these peptides and peptidomimetics would be used. As Applicant points out, the assays to test peptides in an in vitro system may be available, but there is no teaching provided nor are there working examples that would lead one of skill in the art to begin to look for "agent" which binds to  $\beta 1$  integrin cell surface receptor wherein the list would be enormously long and varied. The art of peptidomimetics is highly complex and involves sophisticated instrumentation and analysis, and as such one of skill in the art would be forced into undue experimentation to practice the claimed invention as broadly claimed.

4B. The use of the trademark e.g. Matrigel has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

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Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

5. No claims are allowed.

6. This is a CPA of applicant's earlier Application No. 09/177, 843. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


7. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242 or (703) 305-3014.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Geetha P. Bansal whose telephone number is (703) 305-3955. The examiner can normally be reached on Mondays to Thursdays and alternate Wednesdays from 7:00am to 4:30 pm and alternate Fridays from 7:00am to 3:30pm. A message may be left on the examiner's voice mail service.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Anthony Caputa, can be reached on (703) 308- 4995.

9. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*May 2, 2002*

  
GEETHA P. BANSAL  
PRIMARY EXAMINER